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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/127,138	07/31/1998	MICHEAL L. GRUENBERG	24731-500E	9760

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/127,138	Gruenberg
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *48, 51, 124, 126, and 127* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *48, 51, 124, 126, and 127* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 48,51,124,126,127 are under consideration. Claims 48,51,124,126,127 have been amended. Claims 18-21,46,47,49,50,52-54,68-71,73-123,125,128-135,153 have been canceled.

RESPONSE TO APPLICANTS ARGUMENTS

2. Regarding applicants comments in pages 13-15 of the amendment filed 12/17/2000, in Paper #12 (amendment filed 2/24/2000) applicant has already elected the invention under consideration and pertinent species without traverse.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 48,51,126,127 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the invention as recited in the claims.

The instant claims encompass a method that uses an agent that can be used to

differentiate leukocytes into Th1 cells. However, the only specific agents to induce Th1 differentiation disclosed in the specification are treatment with antiIL-4 antibody or interferon gamma or IL-12. The claims encompass use of a wide variety of undisclosed agents in the claimed method. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 48,124,126,127 are rejected under 35 U.S.C. 102(e) as being anticipated by June et al. (US Patent 6,352,694).

June et al. teach that Th1 cells can be produced and expanded using treatment of CD4+ cells with antiCD3 antibody and antiCD28 antibody (see column 30, penultimate paragraph). Said method does not use exogenous lymphokines. June et al. teach that the CD4+ cells used can be antigen specific (see column 30, first complete paragraph). The antiCD3 and antiCD28 antibodies taught by June et al. are mitogenic monoclonal antibodies (se Example 14). The cells can be further isolated or purified (see column 19). The starting material can be T cells isolated from PBL (see column 19). The cells can be expanded to reach 10^{11} cells (see column 28, lines 1-5). The cells are homogenous because June et al. teach that this method selectively expands Th1 cells (see column 30, penultimate paragraph).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 48,51,124,126,127 are rejected under 35 U.S.C. 103(a) as being unpatentable over June et al. (US Patent 6,352,694) in view of Sedar et al.

June et al. teach that Th1 cells can be produced and expanded using treatment of CD4+ cells with antiCD3 antibody and antiCD28 antibody (see column 30, penultimate paragraph). Said method does not use exogenous lymphokines. June et al. teach that the CD4+ cells used can be antigen specific (see column 30, first complete paragraph). The antiCD3 and antiCD28 antibodies taught by June et al. are mitogenic monoclonal antibodies (~~se~~ see Example 14). The cells can be further isolated or purified (see column 19). The starting material can be T cells isolated from PBL (see column 19). The cells can be expanded to reach 10^{11} cells (see column 28, lines 1-5). June et al. do not teach the method of claim 51. Seder et al. teach that Th1 (eg. interferon gamma producing cells derived from CD4+ T cells) can be produced by treating CD4+ cells with interferon gamma (see page 10190, second column, last paragraph, first sentence). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because June et al. teach the claimed method except for the use of prior treatment with interferon gamma treatment (an agent that causes Th1 differentiation), while Seder et al. teach that Th1 (eg. interferon g producing cells derived from CD4+ T cells) can be produced by treating CD4+ cells with interferon gamma (see page 10190, second column, last paragraph, first sentence).

9. Claims 48,51,124,126,127 are rejected under 35 U.S.C. § 103 as being unpatentable over Babbitt et al. (US Patent 5,766,920) in view of Martin et al. (US Patent 5,814,295).

Babbitt et al. teach methods for producing Th1 cells, wherein patient mononuclear cells are removed and expanded in vitro (see columns 5 and 6) and used for autologous cell therapy (see abstract). Babbitt et al. teach that said cells can be grown in the absence of IL-2 (see column 17, last paragraph). The method taught by Babbitt et al. uses IFN g enriched supernatants and OKT3 (eg. antiCD3 antibody) to produce Th1 populations (see columns 5 and 6). The administered OKT3 consists of "mitogenic monoclonal antibodies" (eg. multiple copies of the same antibody). Babbitt et al. teach that autologous expanded Th1 cells are reinfused to treat autoimmune disease (see column 2, first complete paragraph). Babbitt et al. do not teach that 10^{10} or 10^{11} cells are used. Martin et al. teach administration of 5 x10^{10} cells in adoptive T cell therapy (see column 11, fifth paragraph).

Routine optimization would result in the use of more (10^{11} cells) or less cells depending on the particular patient (eg. see Table 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Babbitt et al. teach the claimed invention except for use of 10^{10} or 10^{11} cells whilst Martin et al. teach administration of 5 x10^{10} cells in adoptive T cell therapy and routine optimization would result in the use of more (10^{11} cells) or less cells depending on the particular patient (eg. see Table 20).

Regarding applicants comments, while Babbitt et al. teach that their method can be used to expand a variety of different T cell populations, Babbitt et al. also teach that their method can specifically be used to expand Th1 type cells (see column 6, penultimate paragraph). The Th1 cells are not an intermediate cell that is used to produce T3CS but are a final product that is administered to humans to treat disease (see column 6, penultimate paragraph, last sentence). Babbitt et al. teach that mononuclear cells are used as the starting material in said method (eg. see column 5, first incomplete paragraph) wherein mononuclear cells are a "leukocyte containing material" or a "material containing mononuclear T lymphoid cells". The method of expanding Th1 disclosed in column 5, first incomplete paragraph does not use IL-2. Martin et al. teach that the art recognized administration of 5 x10^{10} cells in adoptive T cell therapy (see column 11, fifth paragraph). Routine optimization would result in the use of more (10^{11} cells) or less cells depending on the particular patient (eg. see Table 20).

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone

number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1900~~ 1600

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Art Unit 1644